connecting member preset with an elasticity which causes the connecting member to elongate longitudinally when the annular elements are in their expanded state" lacks original support because the original specification 'did not contemplate presetting the elasticity to elongate as presently claimed'. As such, the Examiner accorded this limitation an October 26, 1999 filing date rather than May 19, 1994 filing date to which it is entitled.

This limitation is, in fact, supported by the disclosure found in US Application 08/246,320 filed May 19, 1994, from which priority is claimed and in particular by FIGs. 11a and 11b of the application when viewed in the context of the original Application as filed. Fig. 11a depicts a stent in an unexpanded state and Fig. 11b depicts the same stent in an expanded state. The stent, as would be recognized by one of ordinary skill in the art, comprises a plurality of annular members, connected by connecting members. It would be further recognized by one of ordinary skill in the art, and as depicted in the figures, that as an annular member radially expands, it decreases in longitudinal length. Connecting members elongate, as shown in Fig. 11b, when the annular members are in their expanded state. As indicated at page 12, lines 14-19 the connecting members and the annular rings of the embodiment shown in FIGs. 11a and 11b may include both a martensitic and an austenitic layer such as is described in the Application starting on page 7, line 10.

As to the issue of preset elasticity being provided for in US Application 08/246,320 filed May 19, 1994, Applicants note that on page 4 of the Final Office Action it is stated that "[I]in the Nitinol disclosure, there is explanation that the shape of elasticity of Figs. 11a and 11b can be preset; see page 5, line 5 to page 6, line 2 and page 12, lines 14-19."

Not only is the limitation of preset elasticity supported by the original May 19, 1994 filing, but one of ordinary skill in the art would recognize that the preset elasticity is an inherent feature of the claimed device. The Federal Circuit has recognized that for a disclosure to be inherent, the missing descriptive matter must necessarily be present in the application's specification such that one skilled in the art would recognize such a disclosure (*Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1159, 47 USPQ2d 1829, 1834 (Fed. Cir. 1998)). In support of the assertion

that the connecting members inherently have a preset elasticity which causes the connecting members to elongate longitudinally Applicants have submitted herewith a Declaration from Prof. Bhattacharya of the California Institute of Technology.

As discussed in the Declaration of Prof. Bhattacharya, the elongation of the connecting members as described in claim 22 occurs because of the preset elasticity of the connecting members which is inherent in a stent having a self-expanding component such as is shown in FIGs. 11a and 11b.

In light of the above, Applicants assert that the feature of "each connecting member preset with an elasticity which causes the connecting member to elongate longitudinally when the annular elements are in their expanded state" as recited in claim 22 is fully supported by the specification as originally filed and FIGs. 11a and 11b in particular. Thus, the §112 rejection to claims 22-32 and 34-35 is overcome and Applicants respectfully request withdrawal of the rejection.

Claim Rejections – 35 USC § 102

Claims 22-32 and 34 were rejected under §102 as being anticipated by Roubin, where the effective filing date of the present claims is October 26, 1999. As indicated above, the present claims have a priority date of May 19, 1994. Because the claims in question claim priority to a date prior to the filing date of the Roubin reference, Roubin cannot be said to anticipate the instant claims. As a result, the rejection is respectfully overcome.

FORMALITIES

If an extension of time is required to make this response timely and no separate petition is enclosed, Applicants hereby petition for an extension of time sufficient to make the response timely. In the event that this response requires the payment of government fees and payment is not enclosed, please charge Deposit Account No. 22-0350.

CONCLUSION

In view of the foregoing it is believed that the present application, with claims 22-32 and 34-35 is in condition for allowance. Early action to that effect is earnestly solicited.

Respectfully submitted,
VIDAS, ARRETT & STEINKRAUS, P.A.

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:	Burmeister et al.
Application No.:	09/427,291
Filed:	October 26, 1999
For:	Improved Tissue Supporting Devices
Examiner:	P. Prebilic
Group Art Unit:	3738

Mail Stop_____
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Docket No.: S63.2-4944-US04

DECLARATION OF KAUSHIK BHATTACHARYA

I Kaushik Bhattacharya state:

1.   I am currently employed by the California Institute of Technology as a Professor of Mechanics & Materials Science in the Division of Engineering & Applied Science. I have been employed by the California Institute of Technology as a Professor, since 2000, as an Associate Professor from 1999-2000 and as an Assistant Professor from 1993-1999 in the Division of Engineering & Applied Science. I earned a Ph.D. in 1991 from the University of Minnesota in Aerospace Engineering and Mechanics and a B. Tech in 1986 from the Indian Institute of Technology, Madras.

2.   I am very familiar with the properties of shape memory materials and have published numerous papers dealing with shape memory materials. I understand that a self-expanding component made from a shape memory material such as self-expanding Nitinol is able to self-expand from an unexpanded state to an expanded state as a result of its elasticity or super elasticity which is inherently preset during the manufacture of the component. I am also

§1.132 Declaration
Page 2

Application No.: 09/427,291
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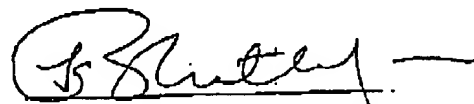
very familiar with the expansion characteristics of stents made from shape memory material, such as self-expanding Nitinol.

3.   I have reviewed US Application 09/427,291. Figs. 11a and 11b of the application show an unexpanded stent and an expanded stent, respectively, with annular elements and connecting members. The specification notes that the stent of Figs. 11a and 11b may be made in accordance with the inventive concepts disclosed in the application. I understand that the inventive concepts disclosed in the application include making the stent of Fig. 11a and Fig. 11b from Nitinol such that the stent has self-expanding properties. As shown in Fig. 11b, when the stent of Fig. 11a expands, the connecting members elongate longitudinally to compensate for the decrease in longitudinal dimension of the annular elements. In light of my familiarity with shape memory and self-expanding materials, I can attest that one of ordinary skill in the art will recognize that the elongation of the connecting members as described above occurs because of the preset elasticity or super elasticity of the connecting members which is inherent in a stent having a self-expanding component of the design shown in Figs. 11a and 11b.

4.   I declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: May 28, 03

Kaushik Bhattacharya Ph.D.

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